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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,190	11/25/2003	Malka Berndt	06530.0317	4220

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EXAMINER	
TOY, ALEX B	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,190	BERNDT, MALKA	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *11 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-29 and 31-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the device, wherein the indicator includes a plurality of indicators must be shown or the features canceled from claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-29, and 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Malchesky (U.S. Pat. No. 5,518,927).

Regarding claim 1, Malchesky discloses a device to perform a medical procedure comprising:

a medical device 20 (Fig. 4); and

an indicator 22 produced directly on the medical device (col. 2, ln. 17-19), the indicator including a chemical capable of undergoing a color change when exposed to a particular environment (col. 1, ln. 1-24),

wherein the indicator is configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment (col. 6, ln. 41-50).

Malchesky discloses that "a functioning portion of the instrument may be constructed of the indicator plastic material." He further discloses that "the region of the material which is impregnated with the color change indicator can be limited to a region having a preselected shape, such as the word 'discard'. The remainder of the material may be ... coated to protect it from the oxidant such that as the indicator region changes color, the word 'discard' or other indicia becomes visible." Since Malchesky

discloses that "a functioning portion of the instrument may be constructed of the indicator plastic material", the coated portion of the indicator plastic material is inherently a portion of the medical device. More specifically, the ring 22 is a functioning portion of the instrument since it inherently functions as a handle for the instrument; and the indicator is produced directly on the ring 22.

Regarding claim 2, Malchesky discloses the device of claim 1, wherein the medical device comprises a handle, a distal end effector, and an elongate portion connecting the handle to the distal end effector (Fig. 4).

Regarding claim 3, Malchesky discloses the device of claims 1 and 2, wherein the indicator 22 is produced directly on the handle (Fig. 4). Since the device is inherently capable of being held at 22, the indicator 22 is produced directly on the handle as claimed.

Regarding claim 4, Malchesky discloses the device of claims 1 and 2, wherein the handle comprises a ring portion and an elongate portion (Fig. 4). The ring 22 (Fig. 6) constitutes a "ring portion" and the shaft covering just distal of the ring 22 constitutes an "elongate portion". Since the instrument is inherently capable of being held at these two locations, these two elements inherently comprise the handle as claimed.

Regarding claim 5, Malchesky discloses the device of claims 1, 2, and 4, wherein the indicator is produced directly on the ring portion 22 (col. 2, ln. 17-24, col. 6, ln. 17-20, and Fig. 4).

Regarding claim 6, Malchesky discloses the device of claim 1, wherein "the region of the material which is impregnated with the color change indicator can be limited to a region having a preselected shape, such as the word 'discard'" (col. 6, ln. 43-46). Since the indicator comprises lettering, the indicator must inherently be printed directly on the medical device.

Regarding claim 7, Malchesky discloses the device of claim 1, wherein the indicator is configured to show a symbol when it undergoes the color change (col. 6, ln. 43-50).

Regarding claim 8, Malchesky discloses the device of claim 1, wherein the particular environment includes a chemical (col. 3, ln. 29-33).

Regarding claim 9, Malchesky discloses the device of claims 1 and 8, wherein the chemical is EtO gas (col. 3, ln. 29-33).

Regarding claim 10, Malchesky discloses the device of claim 1, wherein the particular environment includes steam (col. 3, ln. 37-40).

Regarding claim 12, Malchesky discloses the device of claim 1, wherein the indicator is configured to be a different color than a portion of the medical device after being exposed to the particular environment (col. 6, ln. 43-50). Again, as stated in the preceding rejection of claim 1, the coated portion of the ring 22 constitutes a portion of the medical device.

Regarding claim 13, Malchesky discloses the device of claim 1, wherein the indicator is produced directly on a surface of the medical device (col. 6, ln. 43-50).

Regarding claim 14, Malchesky discloses the device of claim 1, wherein the indicator includes a plurality of indicators (col. 6, ln. 13-16). As claimed, applicant does not specify that the plurality of indicators must be arranged independently of each other and not layered on top of each other. In accordance with Malchesky, each different pigment layer constitutes a different indicator. For example, a layered sequence of green-yellow-red would indicate different stages of use.

Regarding claim 15, Malchesky discloses the device of claims 1 and 14, wherein each of the plurality of indicators undergoes a color change different from the other of the plurality of indicators (col. 6, ln. 13-16, 24-28). For example, in a layered sequence of green-yellow-red: the green indicator changes to yellow; the yellow indicator changes to red; and the red indicator changes to the translucent ring to reveal the word "discard".

Regarding claim 16, see the rejections of claims 1-3 and 12-13.

Regarding claim 17, see the rejections of claims 16 and 6.

Regarding claim 18, see the rejections of claims 16 and 7.

Regarding claim 19, see the rejections of claims 16 and 8.

Regarding claim 20, see the rejections of claims 16, 19, and 9.

Regarding claim 21, see the rejections of claims 16 and 10.

Regarding claim 22, see the rejections of claims 16 and 14.

Regarding claim 23, see the rejections of claims 16, 22, and 15.

Regarding claim 24, see the rejections of claims 1 and 12.

Regarding claim 25, see the rejections of claims 24 and 6.

Regarding claim 26, see the rejections of claims 24 and 7.

Regarding claim 27, see the rejections of claims 24 and 8.

Regarding claim 28, see the rejections of claims 24, 27, and 9.

Regarding claim 29, see the rejections of claims 24 and 10.

Regarding claim 31, see the rejections of claims 24 and 12.

Regarding claim 32, see the rejections of claims 24 and 14.

Regarding claim 33, see the rejections of claims 24, 2, and 3.

Regarding claims 34, see the rejection of claim 1.

Regarding claims 35, see the rejection of claims 16 and 1.

Regarding claims 36, see the rejection of claims 24 and 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 16, 24, 37-47, and 49-60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Quattrocchi (U.S. PGPub 2002/011931 A1).

Regarding claim 1, Quattrocchi discloses a device to perform a medical procedure comprising:

a medical device 20 (Fig. 1); and

an indicator 27-29 produced directly on the medical device (pg. 2, ¶ 21 and Fig. 2), the indicator including a chemical capable of undergoing a color change when exposed to a particular environment (pg. 2, ¶ 20),

wherein the indicator is configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment.

The examiner takes Official Notice that it is well-known in the art for pregnancy tests to be of a unitary white color; the medical device/surface of the handle and the indicator/test strip material are both white before the indicator is exposed to the urine sample.

In the alternative, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to have made the indicator of Quattrocchi to be configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment because applicant

has not disclosed any criticality or unexpected result. It is clearly obvious to make the entire device initially white in order to easily recognize and view any color changes after testing the sample. Furthermore, one of ordinary skill in the art would have expected applicant's invention to perform equally well with Quattrocchi's device because both devices allow one to recognize color changes after testing a sample.

Regarding claim 16, Quattrocchi discloses a medical device comprising:

a handle 21 (Fig. 1);

a distal end effector 24 (Fig. 1);

an elongate portion connecting the handle to the distal end effector (Fig. 1); and

a visual indicator 27-29 produced directly on a surface of the handle (Fig. 2),

wherein the indicator includes a chemical configured to be substantially the same color as the surface of the handle before being exposed to a particular environment (See the preceding rejection of claim 1).

wherein the chemical is configured to undergo a color change to a different color than the surface of the handle after being exposed to the particular environment (See the preceding rejection of claim 1).

Regarding claim 24, see the preceding rejection of claim 1.

Regarding claims 37-39, Quattrocchi discloses the device and method of claims 1, 16, and 24, wherein the chemical is configured to change to a first color when exposed to a first environment and change to a second color different from the first color when exposed to a second environment different from the first environment (pg. 2, ¶ 20).

Regarding claims 40-42, Quattrocchi discloses the device and method of claims 1, 16, and 24, wherein the indicator is configured to change color after a single exposure to the particular environment (pg. 2, ¶ 19).

Regarding claim 43, see the preceding rejections of claims 1 and 37.

Regarding claim 44, Quattrocchi discloses the device of claim 43. In addition, printing would have been an obvious means to one of ordinary skill in the art for applying the indicator to the testing strip.

Regarding claim 45, see the preceding rejections of claims 1 and 43.

Regarding claim 46, see the preceding rejections of claims 16 and 43.

Regarding claim 47, Quattrocchi discloses the device of claim 43, wherein the indicator includes a plurality of indicators 27-29 (Fig. 20).

Regarding claim 49, see the preceding rejections of claims 1 and 43.

Regarding claim 50, see the preceding rejections of claims 1, 40, and 43.

Regarding claim 51, see the preceding rejections of claims 1, 16, and 43.

Regarding claim 52, see the preceding rejections of claims 1, 43, and 47.

Regarding claim 53, Quattrocchi discloses the device of claim 52, wherein a first of the plurality of indicators (positive control indicator 28) is configured to change color when exposed to a first environment (correctly performed test) and not change color when exposed to a second environment (incorrectly performed test) different from the

first environment, and a second of the plurality of indicators (negative control indicator 29) is configured to change color when exposed to the second environment (incorrectly performed test) and not change color when exposed to the first environment (correctly performed test) (pg. 2, ¶ 20).

Regarding claim 54, see the preceding rejections of claims 52 and 44.

Regarding claim 55, see the preceding rejections of claims 52, 1, and 16.

Regarding claim 56, see the preceding rejections of claims 52, 1, and 16.

Regarding claim 57, see the preceding rejections of claims 52 and 48.

Regarding claim 58, see the preceding rejections of claims 52 and 49.

Regarding claim 59, see the preceding rejections of claims 52 and 40.

Regarding claim 60, see the preceding rejections of claims 52 and 51.

Claims 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quattrocchi ('931) in view of Pronovost (U.S. Pat. No. 5,786,220).

Regarding claim 48, Quattrocchi discloses the device of claims 43 and 47. The claim differs in calling for each of the plurality of indicators to undergo a color change different from the other of the plurality of indicators. Pronovost, however, teaches a similar testing device, wherein each of the plurality of indicators undergoes a color change different from the other of the plurality of indicators in order to make reading the results easier (col. 3, ln. 22-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made each of the plurality of indicators of Quattrocchi to undergo a color change different from the other

of the plurality of indicators in view of the teaching of Pronovost in order to make reading the results easier.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

US 4382063 A	USPAT	Romito; Vincent A. et al.
US 5359993 A	USPAT	Slater; Charles R. et al.
US 5384264 A	USPAT	Chen; Ted M. et al.
US 5602040 A	USPAT	May; Keith et al.
US 5739041 A	USPAT	Nazareth; Albert et al.
US 5900379 A	USPAT	Noda; Hiroto et al.
US 6140136 A	USPAT	Lee; Jin Po
US 6218189 B1	USPAT	Antonoplos; Patricia A. et al.
US 20040049172 A1	US-PGPUB	Root, Thomas V. et al.
US 20040253142 A1	US-PGPUB	Brewster, Barry Sinclair et al.
US 20040265778 A1	US-PGPUB	Kliff, Howard et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
4/28/06

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